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10/804,595	03/19/2004	Eric W. Rubie	55508-301656	9551

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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08/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/804,595

Applicant(s)

RUBIE ET AL.

Examiner

Cheryl Miller

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53 is/are allowed.
- 6) ☒ Claim(s) 1-15, 23-47, 51-52 and 54 is/are rejected.
- 7) ☐ Claim(s) 16-22 and 48-50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-50 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 is indefinite since the claim from which it depends (claim 5) requires the middle portion to have a smaller width than the upper and lower portions. It is unclear how the profile may be convex if the middle portion has a lesser extent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3738

Claims 1-6, 8-15, and 23-24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Merlette et al. (US 6,398,818 B1, cited previously). See figures 2-4 particularly.

Claims 1-4, 10, 11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Allard et al. (US 5,509,937). Allard discloses a prosthesis comprising a lower plate (27b), upper plate (27a), and an elastomeric layer (25) disposed there between. Allard discloses the elastomeric layer (25) to extend *substantially* over the lower plate (extend completely over portions 24 and 26, thus over substantially the plate). Allard discloses the plates to be *generally uniformly* spaced from one another (thickness of 25 is constant over most of the plate surfaces; see fig.4, 7). Allard has shown the elastomeric layer (25) to extend to the periphery of the plates (see fig.4). Allard discloses the plates to be made of carbon fibers (col.4, lines 1-3).

Claims 1-4, 10, 11, 14, 15, 23, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Merlette (US 5,156,631). Merlette discloses a prosthesis (fig.1) comprising a lower plate (15), upper plate (13), and an elastomeric layer (21) disposed there between. Merlette discloses the elastomeric layer (21) to extend *substantially* over the lower plate (fig.1; disclosed to extend from toe tip backward, col.4, lines 60-64). Merlette discloses the plates to be *generally uniformly* spaced from one another, wherein an anterior portion is uniformly spaced and a posterior portion has increasing spacing (fig.1; constant spacing between upper 13a+14 and lower 19+18 and increasing spacing between 12 and 17; col.4, lines 24-34). Merlette discloses the plates to be made of high strength fibers (col.4, lines 35-45) and the elastomeric layer to be polyurethane (col.4, lines 56-58).

Claims 25-32, 34-35, 38-40, 42-44, 47, and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Pitkin et al. (US 6,290,730 B1). In one interpretation of Pitkin, claims 25-

Art Unit: 3738

28, 34, 35, 38, 39, 42-44, 47, and 51 have been applied: Pitkin discloses a curved upper plate (22; fig.3), a lower plate (14) at least as long (see fig.2), and an attachment device (24 or 24+26) mounted on the upper plate (22) and conforming to the sloped portion of the upper plate (see fig.3; dome conforms to the curve of upper plate 22). Pitkin discloses a mounting portion (upper surface of dome 24 or pyramid 26). Pitkin discloses attachment of the attachment device (24+26) to the upper plate (22) by fasteners (18, 20). Layer 16 may be considered either the backing component or the elastomeric layer. The elastomeric layer extends over a *substantial portion* of the lower plate (fig.1, 2)

In a different interpretation of Pitkin, claims 25, 26, 28-32, 34, 38-40, and 47 have been applied: Pitkin discloses a curved upper plate (16), a lower plate (14) at least as long (see fig.2), and an attachment device (22 or 12) mounted on the upper plate (16) and conforming to the sloped portion of the upper plate (see figs). Pitkin discloses a mounting portion (the horizontal surface top of 22) having a pyramid adapter (26).

Claims 25-28, 33-36, 38-40, 47, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. (US 5,116,384). Wilson discloses a curved upper plate (48), a lower plate (12), and an attachment device (32) mounted to the upper plate conforming to the slope of the plate (shown sloped in figs.2, 4, 6). Wilson discloses a horizontal mounting portion (see fig.5, where a portion of adapter 32 is shown flat where pyramid sits). Wilson discloses the attachment device (32) is bonded (by 74; col.5, lines 49-53) and mechanical fastened (by 36) to the plate (48). Wilson discloses a backing component (28+30; see fig.5) on the lower surface of the upper plate (48), the attachment device (32) attaches to the upper plate (48) by a fastener (36) in the backing component (28+30).

Art Unit: 3738

Claims 25-27, 29-31, 34-42, 45, 47, and 51-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips (US 5,181,932). In one perspective, Phillips anticipates claims 25-27, 29-31, 34-42, 45, 47, 51, and 52 as so: Phillips discloses a curved upper plate (50), a lower plate (12) as long as the upper plate (see plate orientations in figs.1, 4), and an attachment device (attachment embodiment 90 seen in fig.6-8 as an alternative to that shown as 32 in fig.4). The attachment device is shown to conform to upper plate sloping in figures 5 and 8. Phillips discloses a backing component (14) and an intermediate elastomeric layer (70) positioned between the upper (50) and lower (12) plates. Phillips discloses two opening for fasteners (98; see fig.8). Phillips attachment device has a weight reducing cutout on the proximal side, chamfer seen on 90 in fig.7 and 8.

In another perspective, Phillips anticipates claims 25-27, 29-31, 34, 38-42, and 47 as so: Phillips discloses a curved upper plate (14), a lower plate (12) as long as the upper plate (see plate orientations in figs.1, 4), and an attachment device (attachment embodiment 90 seen in fig.6-8 as an alternative to that shown as 32 in fig.4). The attachment device is shown to conform to upper plate sloping in figures 5 and 8. Phillips discloses an elastomeric layer (70, 72) inbetween the upper and lower plates.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3738

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allard et al. (US 5,509,937). Allard discloses the prosthesis to have an elastomeric layer, however is silent to mention any specific materials or the thickness of the material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the elastomeric layer of polyurethane and have the uniform thickness to be about 2 mm, since it has been held to be within the general skill of a worker in the art to select a known material (polyurethane) on the basis of its suitability (elastomeric) for the intended use as a matter of obvious design choice, *In re Leshin*, 125 USPQ 416, and also since such a dimension would have involved only a mere change in the size of a component (thickness). A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claim 25, 42, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US 5,800,569, cited in IDS). Phillips discloses the a lower leg prosthesis substantially as claimed. Phillips discloses an upper plate (112), lower plate (110), attachment device (118), elastomeric interlayer (114), backing component (126) below the upper plate and within the elastomeric layer (see fig.5). Phillips discloses all elements of the claim, however does not disclose the upper plate to be curved. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a curved vs. planar upper plate, such that it would provide more flexibility during gait. Curved plates are common in the foot art, see US 5,156,631, US 5,116,384, and US 5,181,932 for example.

Allowable Subject Matter

Claims 53 allowed.

Art Unit: 3738

Claims 16-22 and 48-50 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

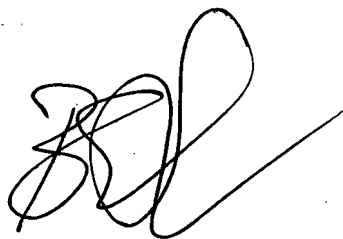
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



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PRIMARY EXAMINER